

Exhibit 13

From: Klontz, Karl C </O=FDA/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=KKLONTZ>
Sent: Tuesday, November 26, 2013 12:21 PM
To: Ostroff, Stephen <Stephen.Ostroff@fda.hhs.gov>
Subject: RE: National Toxicology Program contact re: OEP

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Yes, this makes sense to me, Steve. Will be interesting to hear what Paul Howard has to say about the feasibility of this.

On another note, I'm still reading the HI manuscript Sarah sent, but I have some somewhat major questions/ concerns about some of the wording. I know she doesn't want to hear them, so I'll keep them restricted to myself, but there's some questionable content from my view in certain spots...

Karl

From: Ostroff, Stephen
Sent: Tuesday, November 26, 2013 12:19 PM
To: Klontz, Karl C
Subject: RE: National Toxicology Program contact re: OEP

I remain curious about why if there are other products on the market that contain aegeline that we've only linked illness to OEP. It may be that it simply has a much larger market share and our systems are too insensitive to identify cases associated with lesser used products. However, it may also be that it's the combination of ingredients in OEP, rather than just the aegeline, that is causing the product.

So if testing was determined to be helpful in explaining what happened, it would seem most appropriate to test aegeline alone and then aegeline in various combinations with the other ingredients of OEP.

From: Klontz, Karl C
Sent: Tuesday, November 26, 2013 12:01 PM
To: Ostroff, Stephen
Subject: RE: National Toxicology Program contact re: OEP

Probably best to wait til Dan gets back so he's in on the initial conversation.

Guess I'm trying to think what the central question is for Paul Howard. Is it something like this: "Is there a role for animal testing in our quest to understand whether aegeline has hepatotoxic properties?"

Or is it more broad, as: "Can animal testing parse the hepatotoxic effects of OEP components?"

Curious what you think.

Karl

From: Ostroff, Stephen
Sent: Tuesday, November 26, 2013 11:54 AM
To: Klontz, Karl C
Subject: RE: National Toxicology Program contact re: OEP

We can either give him a call together or wait until Dan gets back on Monday and let him weigh in. What do you think?

From: Klontz, Karl C
Sent: Tuesday, November 26, 2013 11:44 AM
To: Ostroff, Stephen
Subject: National Toxicology Program contact re: OEP

Steve,

Wanted to ask you about your thoughts in terms of consulting the National Toxicology Program contact (Paul Howard) in terms of next steps on bringing in animal testing re: OEP. Are we planning to touch base with them?

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Karl